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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/602,330

06/23/2003

Clarence Nathaniel Ahlem

202.2D2

9052

26551 7590 09/11/2007  
HOLLIS-EDEN PHARMACEUTICALS, INC.  
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EXAMINER

RADIO, BARBARA P

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

09/11/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/602,330

Applicant(s)

AHLEM ET AL.

Examiner

Barbara P. Badio, Ph.D.

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 25-28 and 119-146 is/are pending in the application.
- 4a) Of the above claim(s) 25-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 119-146 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____                                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____   | 6) <input type="checkbox"/> Other: ____                           |

**First Office Action on the Merit of a RCE**

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 8, 2007 has been entered.

***Status of the Application***

2. Claims 25-28 and 119-146 are pending in the present application. Claims 25-28 stand withdrawn from further consideration as being drawn to a nonelected invention.

***Claim Rejections - 35 USC § 102***

3. The rejection of claims 119, 130, 139 and 141 under 35 USC 102(b) over Lorie (US 5,461,042 or US 5,387,583) is withdrawn.

***Claim Rejections - 35 USC § 103***

4. The rejection of claims 119-146 under 35 USC 103(a) over Lorie (US 5,461,042 or US 5,387,583) in view of Carr (J. Neuroimmunology, 1998) in combination is maintained.

Applicants maintain their traversal of the rejection for reasons of record. In particular, applicants argue the rejection is based on hindsight. Applicant also argues non-obviousness based the declaration filed February 21, 2007 and references of record. Applicant's argument were considered but not persuasive for the following reasons.

Applicant's argument and the examiner's response to said argument are of record.

Briefly, the claimed invention is drawn to the use of androstenediol to treat or ameliorate immune suppression in human. The art teaches the use of androstenediol to enhance the protective response of the immune system against suppressive influences such as radiation, viral infection, etc. and, thus, the claimed invention is prima facie obvious. The discovery that said enhancement is due to an increase in the number or activity of neutrophils in circulation in the human does not lend patentability to the claimed process because said is inherent to the compound.

The instant claims also recite the administration of the compound "once daily for 4, 5, 6 or 7 consecutive days". Said recitation is not a patentable distinction because the determination of a treatment regimen is routine in the medical art and, thus, well within the level of skill of the ordinary artisan in the art at the time of the present invention.

For these reasons and those given in previous Office Actions, the rejection of claims 119-146 under 35 USC 103(a) over Lorie (US 5,461,042 or US 5,387,583) in view of Carr (J. Neuroimmunology, 1998) in combination is maintained.

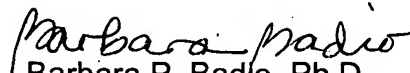
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***Telephone Inquiry***

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Barbara P. Badio, Ph.D.  
Primary Examiner  
Art Unit 1617

BB  
September 5, 2007